



PATENT
Customer Number 22,852
Attorney Docket No. 2405.0167

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Mads Liendgaard Vigh et al.) Group Art Unit: 1623
Serial No.: 09/255,655) Examiner: H. Owens, Jr.
Filed: February 23, 1999)
For: USE OF D-TAGATOSE AS A)
PREBIOTIC FOOD)
COMPONENT)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

**SUBMISSION FILED WITH REQUEST FOR CONTINUED
EXAMINATION UNDER 37 C.F.R. § 1.114**

Reconsideration of this application in view of the file record and the following
remarks is respectfully requested.

In the remarks communicated in the Advisory Action of March 2, 2001, it was
observed that:

With regards to the "selective" production of butyrate, the
prior art (Mortensen et al. and Macfarlane et al) has set forth
that monosaccharides or ketohexoses serve as a substrate
for the production of Short Chain Fatty Acids such a butyrate
and also allow for the growth of commensalistic indigenous
flora such as Lactobacilli.

The present invention is directed to a method for selectively inducing production
of butyrate in the human colon and for selectively stimulating growth of Lactobacilli and
lactic acid bacteria in the human colon by administering D-tagatose. To establish a

prima facie case of obviousness, the Office must show motivation to combine prior art teachings to achieve applicants' claimed invention and must show a reasonable predictability of success in achieving the results flowing from applicants' invention. Neither Mortensen et al. nor Macfarlane et al., alone or in combination, teach or suggest that the administration of D-tagatose will produce the selective effects recited in the claims. While it may be generally recognized in the prior art that monosaccharides and ketohexoses may serve as substrate for the production of SCFAs and have been associated with the growth of certain bacteria, that is not the claimed invention. Moreover, Mortensen et al. (1) not only fails to address the effects of D-tagatose, (2) only speculates (Abstract) that "saccharide fermentation always results in formation of acetate, and that the relative production of acetate, propionate and butyrate is related to the monosaccharide composition of dietary fiber available for colonic bacteria," and (3) shows (Figures 1 and 2) that there is a lack of predictability of the amounts of various SCFAs that are produced *in vitro* by several mono- and disaccharides. As noted in *In re Dembicza*k, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999), the showing of motivation must be clear and particular. Where is the clear and particular motivation to use D-tagatose to obtain the selective effects in the human colon recited in the instant claims?

It was further noted in the Advisory Action that:

Mortensen et al. teaches that a substantial capacity for enhancement of the Short Chain Fatty Acid (propionate and butyrate specifically) production is available when sufficient amounts of an appropriate substrate are present (p. 324, paragraphs 2); therefore, D-tagatose is not alone in the production of butyrate in the human colon. . .

Again, where is the evidence that the prior art recognizes that D-tagatose is "an appropriate substrate" for the selective production of butyrate and selective growth of

lactobacilli and lactic acid bacteria in the human colon? Even *in vitro*, Macfarlane et al. clearly shows that the level of butyrate production is unpredictable among various saccharides - how can this lead to motivation to use D-tagatose? Even if, as the Office observed, "D-tagatose is not alone in the production of butyrate in the human colon," how is this even relevant as to motivation to select D-tagatose, or predictability that it will have the selective effects recited in these claims? Only applicants disclosure provides this information, but this disclosure cannot be relied on to support a *prima facie* case of obviousness.

Finally, the Office stated that:

Zehner clearly teaches that the state of the art has recognized the fermentation of D-tagatose by human microflora, specifically *Lactobacillus casei* (col. 2, lines 56-67). Zehner also teaches that this fermentation could be beneficial if it is slow in the human gut and produces non-caloric metabolites (col. 2, line 67 - col. 3, line 3).

However, the mere fact that some degradation of D-tagatose in the human colon can be expected, or that fermentation of D-tagatose by *Lactobacillus casei* has been observed in one study, does not provide motivation to select D-tagatose to produce the selective effects recited in the claims, and does not provide any predictability that these claimed effects would occur. It may be obvious to select any saccharide to see what effects would occur, but a mere "obvious to try" rationale is insufficient to establish a *prima facie* case of obviousness, particularly when it is coupled (as here) with an utter absence of any predictability of achieving the recited selective effects. See *In re Yates*, 211 USPQ 1149, 1151 (CCPA 1981).

Prompt and favorable reconsideration of this application is respectfully requested.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: March 23, 2001

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